

ADVANCED ANTACID REGULAR STRENGTH- aluminum hydroxide, magnesium hydroxide, dimethicone liquid

STRATEGIC SOURCING SERVICES LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SUNMARK ANTACID ORIGINAL

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200mg (equivalent to dried gel, USP)

Magnesium hydroxide 200 mg

Simethicone 20mg

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Directions

- shake well before use
- adults and children 12 years and older: take 2 to 4 teaspoonfuls between meals, at bedtime, or as directed by a doctor
- do not take more than 24 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks
- children under 12 years: ask a doctor

Other information

- **each 5 mL teaspoonful contains:** magnesium 85 mg, sodium 1 mg
- protect from freezing
- store at room temperature
- keep tightly closed

Inactive ingredients

benzyl alcohol, butylparaben, flavor (contains alcohol), hydroxyethylcellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

package label

Sunmark

compare to active ingredients of the Regular Strength Mylanta®*

NDC 49348-153-39

advanced

antacid

Regular Strength

antacid/antigas

Alumina, Magnesia

and Simethicone

Oral Suspension

Fast acting

soothing relief of

heartburn,

acid indigestion,

sour stomach,

pressure & bloating

ORIGINAL FLAVOR

Alcohol 0.15%

12 FL OZ (355 mL)



Compare to the active ingredients of the Regular Strength Mylanta®

NDC 49348-153-39

advanced antacid

Regular Strength Antacid/Anti-Gas

Alumina, Magnesia and Simethicone Oral Suspension

Fast acting soothing relief of heartburn, acid indigestion, sour stomach, pressure & bloating

ORIGINAL FLAVOR

12 FL OZ (355 mL)

Alcohol 0.15% 273-05122-0 REV0116

Drug Facts TAMPER EVIDENT: Do not use if breakaway band on bottle cap is missing or broken.

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200 mg (equivalent to dried gel, USP)	Antacid
Magnesium hydroxide 200 mg	Antacid
Simethicone 20 mg	Antigas

Purpose

Uses relieves • heartburn • sour stomach • acid indigestion • the symptoms referred to as gas

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- kidney disease • a magnesium-restricted diet

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*This product is not manufactured or distributed by the owner of the registered trademark MYLANTA®.

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MSKESON

973-05112-0 REV0116

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ADVANCED ANTACID REGULAR STRENGTH

aluminum hydroxide, magnesium hydroxide, dimethicone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-153
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)					
WATER (UNII: 059QF0KO0R)					
SACCHARIN SODIUM (UNII: SB8ZUX40TY)					
SORBITOL (UNII: 506T60A25R)					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49348-153-39	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2012		
Marketing Information					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final		part331	06/01/2012		

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Registrant - GCP Laboratories (965480861)

Establishment			
Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(49348-153)

Revised: 12/2019

STRATEGIC SOURCING SERVICES LLC